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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 781,046	02 08 2001	Kangsheng Wang	258 193	9275

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EXAMINER

TON, THALAN N

ART UNIT PAPER NUMBER

1632

DATE MAILED: 04 26 2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/781,046

Applicant(s)

WANG, KANGSHENG

Examiner

Thaia N. Ton

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-26 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 5-7, 8-13 and 14-21 drawn to a method for delivering a polynucleotide into a human stem cell by associating the polynucleotide to a human sperm cell through a linker and effecting *in vitro* fertilization of a human oocyte with the human sperm cell to form a zygote, a vector comprising a human sperm cell and a polynucleotide linked to the human sperm cell through a linker, and ES stem cells, classified in class 800, subclass 8+ and class 435, subclass 320.1, for example.
- II. Claims 2 and 4, drawn to methods for delivering a polynucleotide into a human stem cell comprising associating the polynucleotide to a human sperm cell through a linker and effecting *in vitro* fertilization of a human oocyte with the human sperm cell to form a zygote, establishing an embryonic stem cell from the zygote, classified in class 800, subclass 8+, for example.
- III. Claim 3 drawn to methods of screening cells from embryonic stem cells for immunological compatibility with a patient, classified in class 435, subclass 4.
- IV. Claims 22-26, drawn to antibodies characterized by having binding affinity to a sperm cells, and wherein a sperm cell bound antibody retains the ability to fertilize an oocyte, classified in class 530, subclass 387.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are distinct because they are of separate uses. The method to make a transgenic human zygote of Invention I is patentably distinct from the methods to culture and establish embryonic stem cells of Invention II.

Invention I and III are distinct because they are of separate uses. The method to make a transgenic human zygote of Invention I is patentably distinct from the method of screening cells from ES cells to test for immunological compatibility with a patient of Invention III.

Inventions I and IV are mutually exclusive and independent. The method to make a transgenic human zygote of Invention I is not required for the antibodies of Invention IV, and vice versa.

Inventions II and III are distinct because they are of separate uses. The method to culture and establish embryonic stem cells of Invention II is patentably distinct from the methods of screening cells from ES cells to test for immunological compatibility with a patient of Invention III as the ES cells can be derived from another source.

Invention II and IV are mutually exclusive and independent. The method to culture and establish embryonic stem cells of Invention II are not required for the antibodies of Invention IV, and vice versa.

Inventions III and IV are mutually exclusive and independent. The methods of screening cells from ES cells to test for immunological compatibility with a patient of Invention III are not required for the antibodies of Invention IV, and vice versa.

The inventions above have acquired a separate status in the art as a separate subject for inventive effort and require independent searches. The search for each

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of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thaian N. Ton whose telephone number is (703) 305-1019. The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off. Should the examiner be unavailable, inquiries should be directed to Deborah Reynolds, Supervisory Primary Examiner of Art Unit 1632, at (703) 305-4051. Any administrative or procedural questions should be directed to Patsy Zimmerman, Patent Analyst, at (703) 305-2758. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-8724.

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